

## BOARD OF PHARMACY

### Final Statement of Reasons

Subject Matter of Proposed Regulations: Ancillary Personnel

Section Affected: Title 16, Section 1793.3

Hearing Date: April 21, 2004

#### Updated Information

None.

#### Summary of Comments Received During the 45-Day Comment Period (February 20, 2004 to April 5, 2004).

In a letter dated March 18, 2004, Mr. Kenneth E. Sain commented that allowing an unlimited number of personnel in a pharmacy is “an invitation to disaster.”

The board disagrees with this comment. The board is aware of no evidence that increasing the number of ancillary personnel in a pharmacy poses any threat to the public. Existing law permits unlicensed personnel only to enter prescription data into the pharmacy computer and to obtain refill authorizations from prescribers. These functions are clerical in nature and require no professional judgment.

Mr. Sain further commented that the proposed regulation places the burden of determining appropriate staffing on the pharmacist.

The board agrees with this comment. The proposed regulation does allow a pharmacist to determine what is appropriate staffing as it relates to unlicensed ancillary personnel.

Mr. Sain further commented that it is inappropriate for a pharmacist to make judgments regarding staffing levels in the pharmacy.

The board disagrees with this comment. As the person responsible for the safe and lawful operation of the pharmacy, the pharmacist on duty is the appropriate person to make this judgment. To make another person responsible for this judgment would provide the authority to make this decision to an individual who is not responsible for the consequences of the decision.

Mr. Sain further commented that the regulation serves the financial interests of pharmacies but does not serve the public interest.

The board disagrees with this comment. The regulation provides pharmacists with the authority to exercise their professional judgment regarding this staffing issue. Furthermore, the public will

benefit from more efficient pharmacy operations where added unlicensed ancillary personnel are appropriate. In many pharmacies, added unlicensed ancillary personnel will allow pharmacists and pharmacy technicians to focus on more complex activities and leave clerical functions to the clerks. The public does have an interest in such efficiencies that will result in faster service or greater availability of a pharmacist to counsel patients.

#### Summary of Comments Received During the Regulation Hearing.

Bruce Young, representing the California Retailers Association, stated that the CRA is supportive of this regulation change. This is another example where the pharmacist-in-charge and managers can determine the staffing need based on the pharmacy practice.

The board agreed with this comment.

Rich Mazzoni, representing Albertson's/Savon, agreed with the comments made by Mr. Young and understands the administrative burden pharmacists face. This regulation change represents a step towards more pharmaceutical care and less paperwork for pharmacists.

The board agreed with this comment.

In oral testimony, Mr. Alan Gordon representing the California Employee Pharmacist Association (CEPA), stated that 400 pharmacists in Southern California do not support the regulation. Mr. Gordon further stated that unlicensed personnel are not as accurate as pharmacists and will perform duties such as checking in stock and cashiering but the pharmacist won't really know what they are doing and this would have an adverse affect on pharmacy operations.

The board disagreed with this comment. The board is unaware of any information indicating that unlicensed personnel are less accurate when performing data entry tasks. Under the regulation such unlicensed personnel are restricted to such data entry tasks and obtaining refill authorizations if allowed by the supervising pharmacists. Furthermore, the regulation specifies that the pharmacist is responsible for both the accuracy of data entered by unlicensed personnel and for determining appropriate numbers of unlicensed personnel in the pharmacy.

In written comments submitted by Mr. Alan Gordon representing CEPA inquires whether the board has a study demonstrating increased patient counseling by pharmacists following the establishment of the pharmacy technician licensing program.

The board is unaware of any such study, but any such study would not be relevant to the regulation. The ratio of pharmacy technicians to pharmacists is established in statute for community pharmacies and in regulation for inpatient pharmacies. This regulation does not address the supervision of pharmacy technicians, it addresses the supervision of unlicensed personnel in the pharmacy. Furthermore, the board did not premise the adoption of this regulation on increasing pharmacist time for patient counseling. Rather the board premised this regulation on increasing the flexibility of pharmacy staffing in response to changes in the healthcare marketplace.

In the same written comment, Mr. Gordon indicated that when the Legislature adopted the pharmacy technician licensing statute, it required a one-technician to one-pharmacist ratio and that the regulation would have prevented the approval of pharmacy technician licensure by the Legislature.

The board disagreed with this comment. The regulation is does not address pharmacy technicians. Furthermore the Legislature, subsequent to the initial statute governing pharmacy technicians, increased the ratio of pharmacy technicians to pharmacists and that the board has the authority to establish the ratio of pharmacy technicians working in inpatient facilities by regulation.

In the same written comment, Mr. Gordon referred to an unpublished 1974 study evaluating the accuracy of pharmacy technicians filling prescriptions. Mr. Gordon concludes from the study that allowing a pharmacist to supervise the number of unlicensed personnel would lead to problems.

The board disagreed with this comment. The study is not relevant to the regulation because the unlicensed personnel governed by the regulation are not pharmacy technicians and are not permitted to fill prescription orders.

In the same written comment, Mr. Gordon indicated a belief that the regulation, taken in conjunction with another pending regulation permitting a pharmacist to be pharmacist-in-charge at two pharmacies, would result in the pharmacy owner determining the number of staff in the pharmacy.

The board disagreed with this comment. The clear language of the regulation provides that the pharmacist determines the number of unlicensed personnel on duty based on the pharmacist's professional judgment.

In the same written comment, Mr. Gordon indicates that the regulation will result in an increase in adverse events in pharmacies.

The board disagreed with this comment. The board is unaware of evidence indicating that granting authority to a pharmacist to determine the number of unlicensed personnel working a pharmacy would result in an increase in adverse events.

Mr. Trent Smith, representing Rite Aid, stated that they support the regulation.

The board agreed with this comment.

Steven Kyle, pharmacist, encouraged the board not to change the regulation because of public safety issues and the factual basis for this regulation is wrong. He added that since this regulation was put in place, pharmacy systems have become more complicated with computers, scanning devices, biometric devices and reading fingerprints.

The board disagreed with this comment. The fact of increased third party coverage for prescription drug costs is well established. The board further responded that improvements in pharmacy technology have allowed some increased efficiency in managing this workload, but

that ultimately third party billing problems and refill requests are still resolved by person to person interaction.

Mr. Kyle further commented that the number of unlicensed ancillary personnel employed to resolve third-party payment issues is not true. He added that in checking with others and from his experience, unlicensed personnel are not resolving third-party complaint issues; technicians are.

The board disagrees with this comment. While it is true that pharmacy technicians can work to resolve third party payment issues, the board has received ample testimony in numerous settings that indicates pharmacy technicians are most commonly employed to assist the pharmacist in filling the prescription order.

Mr. Kyle further commented that an unlimited number of pharmacy technicians can input data into the computer system but there is a misunderstanding that under section 1793.7 the number of technicians is restricted to those who perform duties outlined in subdivision (a) dealing with manipulation of and counting drugs.

The board disagrees with this comment. Section 4115 of the Business and Professions Code clearly limits the number of pharmacy technicians that may be supervised by a pharmacist regardless of the functions performed by the pharmacy technician. That restriction is not limited to the number of technicians who may count and manipulate drugs.

Mr. Kyle further commented that this regulation would place an unlimited number of personnel in the pharmacy that the board has no control over compared to pharmacy technicians who are licensed and must meet educational and training requirements.

The board disagreed with this comment. The central issue of the regulation is to have the pharmacist be in control of pharmacy personnel. The board's authority to enforce the Pharmacy Law is not equivalent to control of personnel. Control of personnel should occur prior to and during the performance of job duties. The board's enforcement authority is limited to imposing sanctions after a violation has occurred. The law clearly makes the pharmacist accountable for the performance of the unlicensed personnel working in the pharmacy and the board can take appropriate enforcement action against the pharmacist, pharmacist-in-charge, and pharmacy owner if appropriate.

Mr. Kyle further commented that the number of pharmacy technicians should not be limited in the pharmacy.

The board disagrees with this comment. The question of pharmacy technician ratios is not the subject of this regulation.

Mr. Kyle further commented that unlicensed and untrained personnel cause more interruptions to the pharmacist. He suggested that companies move the function of processing through third parties to a central location if this function becomes a burden.

The board agrees with this comment. Staff can cause interruptions to the work of any supervisor and it is incumbent on the supervisor to properly train staff to minimize unnecessary interruptions. Furthermore, the regulation does not preclude the adoption of a central processing system if that is appropriate.

Mr. Kyle further commented that this amendment will not add more personnel to the pharmacy and that large companies will not increase their labor force but will instead shift the work and use clerks because it is less expensive.

The board agrees with this comment. The regulation is designed to provide pharmacies with greater flexibility in staffing.

Mr. John Cronin, representing the California Pharmacists Association (CPhA), stated that the CPhA has a specific policy that supports this regulation change. The CPhA House of Delegates debated this issue and many of the issues raised were also issues raised by CPhA House of Delegates but the outcome was to support the change.

The board agrees with this comment.

Ms. Orrette Quandt, representing Longs Drugs, stated that it is usually the pharmacy technician who is assisting the pharmacist with the count, pour, lick and stick functions. The responsibilities to assist patients rest with the clerk/typist who typically addresses insurance issues. Removing the clerk typist from the computer places the burden on the pharmacist to start entering prescriptions into the computer. Shifting the pharmacist or the pharmacy technician to handle the third party issues disrupts the process of filling and verifying prescriptions.

The board agrees with this comment.

Ms. Quandt stated that the reason for this regulation change is to provide greater assistance to patients. She added that 10 years ago pharmacies did not have the insurance issues and the number of third-party plans that they have now which increased the difficulty in filling prescriptions.

The board agrees with this comment.

Local Mandate:

None.

Business Impact:

The board has determined that the proposed regulatory action would have no significant adverse impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

Consideration of Alternatives:

The board has determined that no alternative presented would be more effective than or as effective as and less burdensome on affected private persons than the proposal described.